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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/756,212

01/12/2004

Shubh D. Sharma

70025-US-22196

1728

55506 7590 01/24/2008  
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EXAMINER

GUPTA, ANISH

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

01/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/756,212

**Applicant(s)**

SHARMA ET AL.

**Examiner**

Anish Gupta

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-34 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 and 14-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION*****Election/Restrictions***

1. Applicant's election of Group I, claims 10, 12, 14, 33-34, where the polypeptide comprises the sequence Ser-Phe-Arg-Trp and the species 7'-amino-heptanoyl-Ser(Bzl)-D-Phe(4-Cl)-Arg-Trp-NH<sub>2</sub> in the reply filed on 11-6-06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

A search was conducted for the species 7'-amino-heptanoyl-Ser(Bzl)-D-Phe(4-Cl)-Arg-Trp-NH<sub>2</sub> and extended to other peptides having the sequence Ser-Phe-Arg-Trp. 7'-amino-heptanoyl-Ser(Bzl)-D-Phe(4-Cl)-Arg-Trp-NH<sub>2</sub>, 7'-amino-heptanoyl-Ser(Bzl)-D-Phe(4-Cl)-Arg-Trp-Ala-NH<sub>2</sub>, 7'-amino-heptanoyl-Ser(Bzl)-D-Phe(4-Cl)-Arg-Trp-Asp-Phe-NH<sub>2</sub>, 7'-amino-heptanoyl-Ser(Bzl)-D-Phe(4-Cl)-Arg-Trp-Asp-NH<sub>2</sub>, 7'-amino-heptanoyl-Ser(Bzl)-D-Phe(4-Cl)-Arg-MeTrp-NH<sub>2</sub>, heptanoyl-Ser(Bzl)-D-Phe(4-Cl)-Arg-MeTrp-NH<sub>2</sub>, 7'-amino-heptanoyl-Ser(Bzl)-D-Phe(4-Cl)-Arg-tryptamide, 7'-amino-heptanoyl-Ser(Bzl)-D-Phe(4-Cl)-Arg-Nme-tryptamide, 7'-amino-heptanoyl-Ser(Bzl)-D-Phe(4-Cl)-Arg-alpha-Me-Tryptamide were found to be free of the prior art. The search was then extended to the linking claims 1-9, 13, and prior art was found that anticipate the claims. Since prior art was found that anticipated the Markush type claims 1, 9 and 13, search was not extended to Markush type claim 11. The MPEP states "On the other hand, should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art

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search, however, will not be extended unnecessarily to cover all nonelected species." See MPEP 803.02. Thus, the search was not extended to claim 7, 11. Furthermore, Since claims 10, 12, 14 were examined in part, only those corresponding to the sequence having Ser-Phe-Arg-Trp, these claims have been withdrawn from consideration. Claims 3-4, 7, 10-12, 14 and 15-32 have been withdrawn from consideration as corresponding to non-elected Groups II-IX.

### Amendments to the Claims

2. In the response filed 11/12/07, Applicants stated that "[i]n the amendment and Restriction Election Without Traverse eFiled on November 6, 2006, independent claims 9, 11 and 13 were amended, such that each claim employs the transition phrase "consisting of." In the present claims, Applicant use the claim identifiers next to claim 9 and 13 as "previously presented." The MPEP states that "The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." See MPEP 714. Thus, it is clear from Applicants remarks and the citation "previously presented" that the claims have not been amended from the previous listing of claims.

3. In the claim listing 11-06-2006, the claim listing prior to the instant amendment, Claim 9 recited for variable S5:

S<sub>5</sub> is Trp, Trp-OH, Trp-NH<sub>2</sub>, Trp-Cys-NH<sub>2</sub>, D-Trp, D-Trp-NH<sub>2</sub>, Trp-Val-NH<sub>2</sub>, 3'-Pya-NH<sub>2</sub>, Phe-NH<sub>2</sub>, (see

first sentence of claim 9, defining S<sub>5</sub>). Note that fourth substituent is Trp-Cys-NH<sub>2</sub> (It

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should be noted that the listing of claims dated 01-12-04, also recited Trp-Cys-NH<sub>2</sub>). The listing of claims presented in the response, dated 11-12-07, does not contain the recitation of Trp-Cys-NH<sub>2</sub>. However, since the claims have been identified as "previously presented," and Applicants response only makes a reference to the amendment "eFiled on November 6, 2006," it has been assumed that the claim should recite and still encompasses Trp-Cys-NH<sub>2</sub> as a substitution for R5.

4. The rejection of claims 1-6, 8, rejected under 35 U.S.C. 102(b) as being anticipated by Youngquist et al. (J. of Am. Chemical Society) is hereby withdraw in light of Applicants amendment.

#### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 9 and 13 remain rejected under 35 U.S.C. 102(a) as being anticipated by Sharma et al. (WO01/13112).

The claims are drawn to peptides of the formula S1-S2 –S3-S4-S5.

The reference teaches the peptide Heptanoyl-Ser(Bzl)-D-Phe(2-Cl)-L-Arg-L-Trp-L-Cys-NH<sub>2</sub> (see page 46, compound No. PL-1915). This meets the limitation of claim 1 where S1 is heptanoyl, S2 is Ser(Bzl), S3 is D-Phe-(2-Cl), S4 is L-Arg, S5 is the dipeptide L-Trp-L-Cys-NH<sub>2</sub>. The reference also teaches the peptide Hpetanoyl-Ser(Bzl)-D-Phe(4-Cl)-

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Arg-L-Trp-Cys-NH<sub>2</sub> (see page 47, compound number 1949). This compound meets the limitation of claim 9 and 13.

### **Response to Arguments**

Applicants argue that the claims are drawn to peptides "consisting of." As such, the claims exclude any element, step or ingredient not specified in the claim. The claims do not recite R5 as Trp-Cys-NH<sub>2</sub> and thus cannot be prior art.

Applicants arguments have been fully considered but have not been found persuasive.

As stated above, the claim listing 11-06-2006, the claim listing prior to the instant amendment, Claim 9 recited for variable S5:

S<sub>5</sub> is Trp, Trp-OH, Trp-NH<sub>2</sub>, Trp-Cys-NH<sub>2</sub>, D-Trp, D-Trp-NH<sub>2</sub>, Trp-Val-NH<sub>2</sub>, 3'-Pya-NH<sub>2</sub>, Phe-NH<sub>2</sub>. (see first sentence of claim 9, defining S<sub>5</sub>). Note that fourth substitution is Trp-Cys-NH<sub>2</sub>. The listing of claims presented in the response, dated 11-12-07, does not contain the recitation of Trp-Cys-NH<sub>2</sub>. However, since the claims have been identified as "previously presented," and Applicants response only makes a reference to the amendment "eFiled on November 6, 2006," it has been assumed that the claim should recite and still encompasses Trp-Cys-NH<sub>2</sub> as a substitution for R5. Thus, since the claims specifically allow for Trp-Cys-NH<sub>2</sub>, the transitional phrase "consisting of" does effect the scope of the claims. The prior art specifically teaches a compound claimed, even with the transitional phrase "consisting of."

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double

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patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 9, and 13 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-54 of U.S. Patent No. 7049398.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to peptides of the formula S1-S2 -S3-S4-S5.

The US patent claims peptides that meet the limitation of the claims. Within the broadest reasonable interpretation of the claims, one of the peptides that falls within the claims is the peptide Heptanoyl-Ser(Bzl)-D-Phe(2-Cl)-L-Arg-L-Trp-L-Cys-NH<sub>2</sub>. This meets the limitation of claim 1 where S1 is heptanoyl, S2 is Ser(Bzl), S3 is D-Phe-(2-Cl), S4 is L-Arg, S5 is the dipeptide L-Trp-L-Cys-NH<sub>2</sub>. The claims also encompass the peptide Hpetanoyl-Ser(Bzl)-D-Phe(4-Cl)-Arg-L-Trp-Cys-NH. Thus, the instant claims and the US patent are not patentably distinct from each other.

7. Claims 1-2, 5, 6-9 and 13 are directed to an invention not patentably distinct from claims 1-54 of commonly assigned US 7049398. Specifically, for the reasons set forth above.

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The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US 7049398, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

### **Response to Arguments**

Applicants argue that all of the peptides of the US patent require the presence of cysteine residue. Applicants have canceled claims 1-8 and remaining claims 9 and 13 recite "consisting of" language. Neither claim 9 nor 13 encompass a peptide with or including cysteine residue in the position corresponding to S5.

Applicants arguments have been fully considered but have not been found persuasive.

As stated above, the claim listing 11-06-2006, the claim listing prior to the instant amendment, Claim 9 recited for variable S5:



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S<sub>5</sub> is Trp, Trp-OH, Trp-NH<sub>2</sub>, Trp-Cys-NH<sub>2</sub>, D-Trp, D-Trp-NH<sub>2</sub>, Trp-Val-NH<sub>2</sub>, 3'-Pya-NH<sub>2</sub>, Phe-NH<sub>2</sub>. (see first sentence of claim 9, defining S<sub>5</sub>). Note that fourth substitution is Trp-Cys-NH<sub>2</sub>. The listing of claims presented in the response, dated 11-12-07, does not contain the recitation of Trp-Cys-NH<sub>2</sub>. However, since the claims have been identified as "previously presented," and Applicants response only makes a reference to the amendment "eFiled on November 6, 2006," it has been assumed that the claim should recite and still encompasses Trp-Cys-NH<sub>2</sub> as a substitution for R<sub>5</sub>. Thus, since the claims specifically allow for Trp-Cys-NH<sub>2</sub>, the transitional phrase "consisting of" does effect the scope of the claims. The prior art specifically teaches a compound claimed, even with the transitional phrase "consisting of."

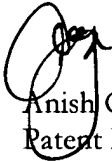
8. Claims 33-34 are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

 1/22/08  
Anish Gupta  
Patent Examiner